May 11, 2020

Pieris Pharmaceuticals Reports First Quarter 2020 Financial Results and Provides Corporate Update

Company to Host an Investor Conference Call on Monday, May 11, 2020 at 8:00 Am Edt

BOSTON, MA / ACCESSWIRE / May 11, 2020 / ***Pieris Pharmaceuticals, Inc. (NASDAQ:PIRS)***, a clinical-stage biotechnology company advancing novel biotherapeutics through its proprietary Anticalin® technology platform for respiratory diseases, cancer, and other indications, today reported financial results for the first quarter of 2020 ended March 31, 2020 and provided an update on the Company's recent and future developments.

"We continue to stay the course with regard to the advancement of our lead assets, PRS-060 and PRS-343, despite the general disruptions caused by the coronavirus pandemic. We have been preparing for the start of the phase 2a trial of PRS-060 with AstraZeneca, which we still anticipate initiating in the second half of this year. Additionally, we have seen further clinical benefit in the monotherapy study of PRS-343, and we will be advancing that asset into a phase 2 study in combination with ramucirumab and paclitaxel in second-line gastric cancer in the second half of this year," said Stephen S. Yoder, President and Chief Executive Officer of Pieris. "I am very proud of the diligence and resolve of our team during these trying times."

- **PRS-060:** Pieris and AstraZeneca are preparing to initiate the phase 2a study of PRS-060/AZD1402 in moderate-to-severe asthmatics in the second half of 2020. The study will be sponsored, funded, and delivered by AstraZeneca and upon completion of that study, Pieris will have the options to co-develop and, subsequently, co-commercialize PRS-060/AZD1402 in the United States.

- **PRS-343:** Based on the totality of the data in the phase 1 dose-escalation monotherapy study of PRS-343, a 4-1BB/HER2 bispecific for HER2-positive solid tumors, Pieris will initiate a phase 2 single-arm study of PRS-343 in combination with ramucirumab and paclitaxel in the second-line of treatment for gastric cancer in the second half of this year. At the active dose levels for which the Company presented interim data last year in cohorts 9 (2.5 mg/kg Q3W) through 11b (8 m/kg Q2W), a partial response was observed in three patients and stable disease was observed in 11 patients as best response out of 21 evaluable patients, translating to an objective response rate (ORR) of 14% and a disease control rate (DCR) of 67%. All three objective responses in these cohorts were observed in cohort 11b, in which disease

stabilization was also observed in three patients out of seven evaluable patients, translating to an ORR of 43% and a DCR of 86%. Additional clinical benefit, including complete response, was also observed in the higher dose cohorts, which are still open for enrollment to generate a larger data set. Pieris plans to present detailed data from both the monotherapy study and atezolizumab combination study at a medical meeting in the second half of this year.

- **Immuno-oncology Pipeline:** Pieris and Servier have been working on furthering the development of PRS-344 and PRS-352. Due to scale-up challenges recently encountered with the manufacture of drug product for PRS-344, a 4-1BB/PD-L1 bispecific, Pieris and Servier have jointly decided to invest in additional CMC activities, given the strategic importance of this program. As a result, Pieris now anticipates filing an IND application for PRS-344 next year. The Company holds exclusive commercialization rights for PRS-344 in the United States and will receive royalties on ex-U.S. sales for this program. Pieris is also focused completing the non-GLP work for PRS-352, a preclinical stage program addressing undisclosed targets, and expects to hand it over to Servier this year. Pieris continues to make progress in the Seattle Genetics collaboration.
- **Preclinical Respiratory Pipeline:** Beyond PRS-060, Pieris continues to advance three discovery programs in its five-program respiratory collaboration with AstraZeneca. Pieris expects AstraZeneca will initiate the fourth discovery program in the collaboration later this year. The Company also continues to advance several proprietary discovery-stage respiratory programs. Pieris expects to share data and rationale for advancement of one of its proprietary programs in the second half of this year.

- **Board of Directors Transition:** Jean-Pierre Bizzari, M.D. transitioned from the Board of Directors to serve as an advisor to the Company on oncology development strategies.

Fiscal Year Financial Update:

Cash Position - Cash, cash equivalents, and investments totaled $86.8 million for the quarter ended March 31, 2020, compared to a cash, cash equivalents, and investments balance of $104.2 million for the quarter ended December 31, 2019. The decrease was due to operating cash expenses, annual bonus payments, and both capital and one-time expenditures associated with the move to a new facility in Hallbergmoos.

R&D Expense - R&D expenses were $12.8 million for the quarter ended March 31, 2020, compared to $14.3 million for the quarter ended March 31, 2019. The decrease in research and development expenses reflects lower manufacturing spending on PRS-344. Partially offsetting this decrease were higher personnel expenses due to an overall increase in R&D headcount and an increase in allocated facility costs due to the new Hallbergmoos site, both associated with the advancement of our preclinical and clinical programs.

G&A Expense - G&A expenses were $4.4 million for the quarter ended March 31, 2020, compared to $4.9 million for the quarter ended March 31, 2019. The decrease in G&A expenses reflects lower personnel costs and a reduction in audit and tax professional fees.

Net Loss - Net loss was $3.6 million or $(0.07) per share for the quarter ended March 31, 2020, compared to a net loss of $10.3 million or $(0.20) per share for the quarter ended

March 31, 2019.

***Conference Call**:*

Pieris management will host a conference call beginning at 8:00 AM EDT on Monday, May 11, 2020, to discuss the first quarter financial results and provide a corporate update. Individuals can join the call by dialing +1-877-407-8920 (US & Canada) or +1-412-902-1010 (International). An archived replay of the call will be available by dialing +1-877-660-6853 (US & Canada) or +1-201-612-7415 (International) and providing the Conference ID #: 13661472.

***About Pieris Pharmaceuticals**:*

Pieris is a clinical-stage biotechnology company that discovers and develops Anticalin protein-based drugs to target validated disease pathways in a unique and transformative way. Our pipeline includes inhalable Anticalin proteins to treat respiratory diseases and immuno-oncology multi-specifics tailored for the tumor microenvironment. Proprietary to Pieris, Anticalin proteins are a novel class of therapeutics validated in the clinic and by partnerships with leading pharmaceutical companies. Anticalin® is a registered trademark of Pieris. For more information, visit www.pieris.com.

***Forward Looking Statements**:*

This press release contains forward-looking statements as that term is defined in Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Statements in this press release that are not purely historical are forward-looking statements. Such forward-looking statements include, among other things, the timing and plans for the phase 2a study of PRS-060/AZD1402; the expected timing and potential outcomes of the reporting by the Company of key clinical data from its programs, references to novel technologies and methods and our business and product development plans, including the advancement of our proprietary and co-development programs into and through the clinic and the expected timing for reporting data, making IND filings or achieving other milestones related to our programs, including PRS-060/AZD1402, PRS-343, PRS-344, and PRS-352 and the expected timing of the initiation of the next stage of PRS-343's development in gastric cancer. Actual results could differ from those projected in any forward-looking statements due to numerous factors. Such factors include, among others, our ability to raise the additional funding we will need to continue to pursue our business and product development plans; the inherent uncertainties associated with developing new products or technologies and operating as a development stage company; our ability to develop, complete clinical trials for, obtain approvals for and commercialize any of our product candidates, including our ability to recruit and enroll patients in our studies; our ability to address the requests of the FDA; competition in the industry in which we operate; delays or disruptions due to COVID-19; and market conditions. These forward-looking statements are made as of the date of this press release, and we assume no obligation to update the forward-looking statements, or to update the reasons why actual results could differ from those projected in the forward-looking statements, except as required by law. Investors should consult all of the information set forth herein and should also refer to the risk factor disclosure set forth in the reports and other documents we file with the SEC available at www.sec.gov, including without limitation the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2019 and the Company's Quarterly Reports on

Form 10-Q.

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PIERIS PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(unaudited, in thousands)

	March 31, 2020	December 31, 2019
Assets:		
Cash and cash equivalents	$ 47,431	$ 62,260
Short term investments	39,333	41,894
Accounts receivable	7,267	6,787
Prepaid expenses and other current assets	4,341	4,072
Total current assets	98,372	115,013
Property and equipment, net	20,344	19,502
Operating lease right-of-use assets	3,170	3,436
Other non-current assets	1,887	3,146
Total Assets	$ 123,773	$ 141,097
Liabilities and stockholders' equity:		
Accounts payable	$ 3,500	$ 5,803
Accrued expenses	6,939	9,944
Deferred revenue, current portion	10,044	11,256
Total current liabilities	20,483	27,003
Deferred revenue, net of current portion	38,560	47,258
Operating lease liabilities	14,924	15,484
Total Liabilities	73,967	89,745
Total stockholders' equity	49,806	51,352
Total liabilities and stockholders' equity	$ 123,773	$ 141,097

PIERIS PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(unaudited, in thousands, except per share data)

	Three months ended March 31,	
	2020	**2019**
Revenues	$ 13,261	$ 8,545
Operating expenses		
Research and development	12,758	14,296
General and administrative	4,359	4,932
Total operating expenses	17,117	19,228
Loss from operations	(3,856)	(10,683)
Interest income	319	506
Other (expense) income, net	(60)	(171)
Net loss	$ (3,597)	$ (10,348)
Basic and diluted net loss per share	$ (0.07)	$ (0.20)
Basic and diluted weighted average shares outstanding	55,212	50,873

SOURCE: Pieris Pharmaceuticals, Inc.

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https://www.accesswire.com/589279/Pieris-Pharmaceuticals-Reports-First-Quarter-2020-Financial-Results-and-Provides-Corporate-Update